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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,052	12/19/2001	Mark C. Estes	G&C 130.36-US-01	5934
22462	7590	06/01/2005	EXAMINER	
GATES & COOPER LLP HOWARD HUGHES CENTER 6701 CENTER DRIVE WEST, SUITE 1050 LOS ANGELES, CA 90045			MENDEZ, MANUEL A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b> 10/025,052	<b>Applicant(s)</b> ESTES ET AL.	
	<b>Examiner</b> Manuel Mendez	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 23-58 and 83-139 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-58 and 83-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

**Claims 23, 41, 89, 106, 123** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "wherein the housing is compact and adapted to be carried by the user" is an indefinite statement because it offers no point of reference for the term "compact" and does not provide any structural limitation to facilitate being carried by the user. The examiner notes for the record that the cited references have apparatuses that can be carried by the user. Accordingly, further changes to the claims in questions are necessary to overcome the indefinite requirements of Section 112.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

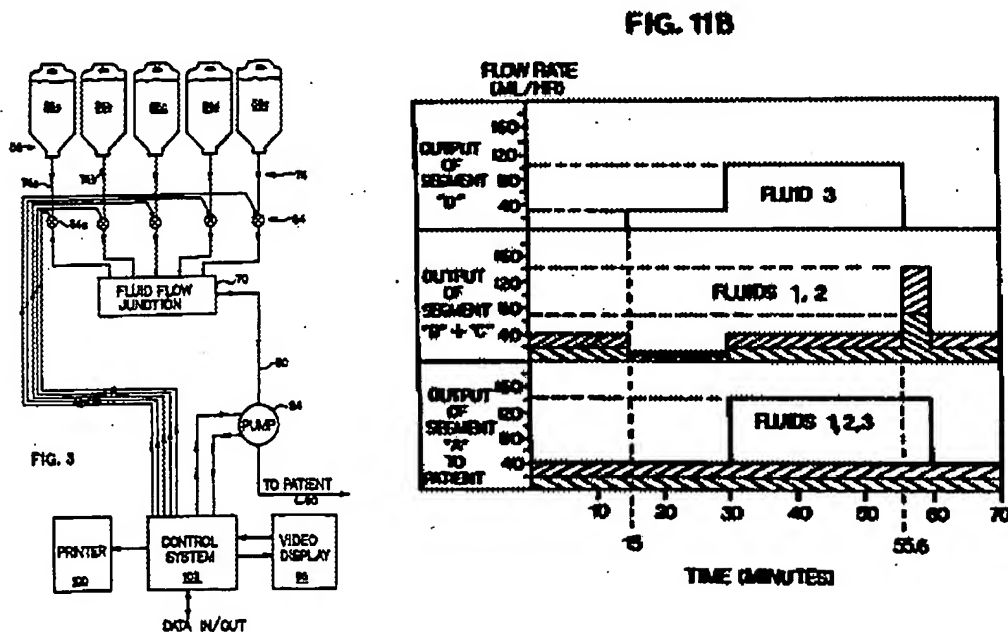
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 23 and 41** are rejected under 35 U.S.C. 102(b) as being anticipated by Orkin, et al.



The cited patent shows in figure 3, an infusion pump (84) and a control system (102) for controlling medication delivery profiles and a plurality of suspend functions

capable of separately suspending a plurality of medication delivery profiles. As figure 11b demonstrates, the apparatus shown in figure 3, is capable of separately suspending the medication profiles of fluids 1, 2, and/or 3.

The examiner notes for the record, that all the structural elements disclosed by the applicant in the cited claims are anticipated by the teachings of Orkin, et al. More importantly, the programming of the control system of Orkin, et al., demonstrates the conventionality of infusing simultaneously multiple medications with different infusion profiles in relation to time, and also, different suspending profiles in relation to time.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 24-40, 42-58, and 83-135** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Orkin, et al.**, and/or **Kern, et al.**, in view of **Lebel, et al.**, U.S. Patent No. 6,562,001, **Lebel, et al.**, U.S. Patent No. 6,810,290, and in further view of **Rodler**.

As discussed above the Orkin, et al., Patent discloses an infusion pump (84) and a control system (102) for controlling medication delivery profiles and a plurality of suspend functions capable of separately suspending a plurality of medication delivery profiles. The Kern, et al., Patent also discloses an infusion pump(s) and a control

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system for controlling medication delivery profiles and a plurality of suspend functions capable of separately suspending a plurality of medication delivery profiles.

Both, the Orkin, et al., and Kern, et al., Patents do not expressly disclose the programming of the respective control systems with basal, square wave, and dual wave profiles, and further more, the use of program safety measures in case of operator error when inputting infusion data. However, these enhancements are conventional in the art as evidenced by the teachings of **Lebel**, et al., U.S. Patent No. 6,562,001, **Lebel**, et al., U.S. Patent No. 6,810,290, and **Rodler**.

Both Lebel, et al., Patents demonstrate the conventionality of programming a pump processor to infuse particular profiles including square wave, dual wave and/or basal. Additionally, in column 2, lines 3-13, the specification of the Rodler Patent suggests that enhancing an infusion system with safety features in case of operator error is well known in the art. Accordingly, the modification of the processors disclosed by the **Orkin, et al.**, and **Kern, et al.**, Patents with algorithms representing basal, square wave, and dual wave profiles, and the addition of safety prevention features would have been considered obvious in view of the teachings of the cited patents.

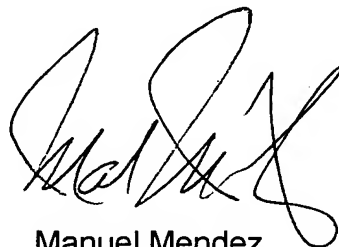
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Manuel Mendez', is positioned above the printed name and title.

Manuel Mendez  
Primary Examiner  
Art Unit 3763

MM